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Filed PCT/PTO 17 JUL 2002

PATENT

Attorney Docket No. 7388/72613

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

NAKAGAWARA, Akira

Application No.: 10/069,723

Filed: February 28, 2002

For: HUMAN 1p36 HOMOZYGOUS DELETION REGION

July 17, 2002

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
Washington, D.C. 20231

Pursuant to 37 CFR 1.97 and 1.98, the references listed on the enclosed Form PTO-1449 and/or Substitute Form PTO-1449 ("Form 1449") are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the references in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the references be entered into the record of the present application and that the Examiner place his or her initials in the appropriate area on the enclosed Form 1449, thereby indicating the Examiner's consideration of each of the references.

The submission of the references listed on the Form 1449 is for the purpose of providing a complete record and is not a concession that the references listed thereon are prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any reference submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the references is not to be taken as a concession that any reference represents art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that any reference is not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

- (X) **within** any one of the following time periods: (a) within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d); (b) within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 of an international application; (c) before the mailing date of a first Office Action on the merits; or (d) before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.
- ( ) **after** (a), (b), (c) or (d) above, but before the mailing date of a final action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and includes *one* of:
- ( ) the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below).
- or
- ( ) the fee of \$180 set forth in 37 CFR 1.17(p) (see "Fees" below).
- ( ) **after** the mailing date of a final action under 37 CFR 1.113 or a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and on or before payment of the issue fee, and includes the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).
- ( ) **after** the mailing date of a Notice of Allowance under 37 CFR 1.311, and on or before payment of the issue fee, and **within** thirty days of receiving each item of information contained in the Information Disclosure Statement, and includes the Statement under 37 CFR 1.704(d) (see "Statement under 37 CFR 1.704(d)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).

NOTE: This is for original applications except applications for a design patent, filed on or after May 29, 2000, wherein a paper containing only an Information Disclosure Statement in compliance with 37 CFR 1.97 and 1.98 is being filed.

#### Copies of the References

- (X) Copies of the references listed on the enclosed Form 1449 are enclosed herewith.
- (X) A copy of the foreign search report is enclosed herewith.

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Application No. 10/069,723

- ( ) The references listed on the enclosed Form 1449 were previously identified in the parent application(s) of the present application, and copies of the references were furnished at that time. Accordingly, additional copies of the references are not submitted herewith, so as not to burden the file with duplicate copies of references. The Examiner is respectfully requested to carefully review the references in accordance with the requirements set out in the Manual of Patent Examining Procedure. In accordance with 37 CFR 1.98(d), the details of the parent application(s) relied upon for an earlier filing date under 35 USC 120 in which copies of the references were previously furnished are set out below:

U.S. APPLICATIONS		Status (check one)		
U.S. APPLICATIONS	U.S. FILING DATE	PATENTED	PENDING	ABANDONED
1.				
2.				
3.				

**Statement under 37 CFR 1.97(e)**

- ( ) The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- ( ) The **undersigned** hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

**Statement under 37 CFR 1.704(d)**

- ( ) The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

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**Fees**

- (X) No fee is owed by the applicant(s).  
( ) The IDS Fee of \$180 under 37 CFR 1.17(p) is enclosed herewith.

**Method of Payment of Fees**

- ( ) Attached is a check in the amount of \$180.00.  
( ) Charge Deposit Account No. 06-1135 in the amount of \$ . (A duplicate copy of this communication is enclosed for that purpose.)

**Authorization to Charge Additional Fees**

- (X) If any additional fees are owed in connection with this communication, please charge Deposit Account No. 06-1135. (A duplicate copy of this communication is enclosed for that purpose.)

**Instructions as to Overpayment**

- (X) Credit Account No. 06-1135.  
( ) Refund

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY

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PTO/SB/08A Substitute for Form PTO-1449  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>		Application Number	10/049,723		
		Filing Date	February 28, 2002		
		First Named Inventor	NAKAGAWARA, Akira		
		Art Unit	To Be Assigned		
		Examiner Name	To Be Assigned		
Sheet	1	of	2	Attorney Docket	7388/72613

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		Call et al., 'Isolation and Characterization of a Zinc Finger Polypeptide Gene at the Human Chromosome 11 Wilms' Tumor Locus', Cell, Vol. 60, Feb. 9, 1990, pp. 509-520	
		Schwab et al., 'Genomic Instability in Ip and Human Malignancies', Genes, Chromosomes & Cancer, 16:211-229 (1996)	
		Fong et al., 'Loss of Heterozygosity for Chromosomes 1 or 14 Defines Subsets of Advanced Neuroblastomas', Cancer Research 52, 1780-1785, April 1, 1992	
		Tanaka et al., 'Suppression of Tumourigenicity in Human Colon Carcinoma Cells By Introduction of Normal Chromosome 1p36 Region', Oncogene (1993), 8, pp. 2253-2258	
		Kuroki et al., 'Accumulation of Genetic Changes During Development and Progression of Hepatocellular Carcinoma: Loss of Heterozygosity on Chromosome Arm 1p Occurs at an Early Stage of Hepatocarcinogenesis', Genes, Chromosomes & Cancer, 13:163-167 (1995)	
		Knudson et al., 'Genetics and the Etiology of Childhood Cancer', Pediat. Res. 10: pp. 513-517 (1976)	
		Hattori et al., 'A Novel Method for Making Nested Deletions and Its Application For Sequencing of a 300 kb Region of Human APP Locus', Nucleic Acids Research, Vol. 25, No. 9, pp. 1802-1808	
		Nakagawara et al., 'Inverse Relationship Between trk Expression and N-myc Amplification in Human Neuroblastomas', Cancer Research 52, March 1, 1992, pp. 1364-1368	
		Nakagawara et al., 'Association Between High Levels of Expression of the TRK Gene and Favorable Outcome in Human Neuroblastoma', The Expression in Neuroblastoma, Vol. 328, No. 12, pp. 847-854	
		Nakagawara, 'TOPICAL TOPIC: The NGF Story and Neuroblastoma', Medical and Pediatric Oncology, 31:113-115 (1998)	
		Nakagawara et al., 'Surgical Aspects of N-myc Oncogene Amplification of Neuroblastoma', Surgery, Vol. 104, No. 1, pp. 34-40	
		'Amplification of N-myc in Untreated Human Neuroblastomas Correlates with Advanced Disease Stage', Science, Vol. 224, pp. 1121-1125	
		Yunis et al., 'Retinoblastoma and Subband Deletion of Chromosome 13', Am. J. Dis. Child, Vol. 132, Feb. 1978, pp. 161-163	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08A Substitute for Form PTO-1449		Application Number 10/049,723	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>		Filing Date February 28, 2002	
		First Named Inventor NAKAGAWARA, Akira	
		Art Unit To Be Assigned	
		Examiner Name To Be Assigned	
Sheet 2	of 2	Attorney Docket 7388/72613	

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		Friend et al., 'A Human DNA Segment With Properties of the Gent That Predisposes to Retinoblastoma and Osteosarcoma', Nature, Vol. 323, 16 October 1986, pp. 643-646	
		Kidd et al., 'Duplication of the DR3 Gent On Human Chromosomes Ip36 and Its Deletion in Human Neuroblastoma' Genomics, 49, May 1998, pp. 385-393	
		White et al., 'A Region of Consistent Deletion in Neuroblastoma Maps Within Human Chromosome 1p36.2-36.3', Proc. Natl. Acad. Sci. USA, 92(12), pp. 5520-5524	
		Barker et al., 'Translocation Junctions Cluster At The Distal Short Arm of Chromosome 1(1p36.1-2) in Human Neuroblastoma Cells', Oncogene, 8(12), December 1993, pp. 3353-3358	
		Iolascon et al., 'Interstitial and Large Chromosome 1p Deletion Occurs in Localized and Disseminated Neuroblastomas and Predicts an Unfavourable Outcome', Cancer Lett, 130(1-2), August 1998, pp. 83-92	
		Nakagawara et al., 'Identification and Characterization of a 500-kb Homozygously Deleted Region AT 1p36.2-36.3 In A Neuroblastoma Cell Line', Oncogene, 19(37), 31 August 2000, pp. 4302-4307	

Examiner Signature		Date Considered	
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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.